Claims

1. A method for evaluating a pharmaceutical composition comprising a drug, said method comprising:

(1) providing a hydrophobic microporous membrane having a plurality of pores, said membrane having a hydrophilic feed side and a permeate side, wherein said feed side of said membrane is in fluid communication with a feed solution, and wherein said permeate side of said membrane is in fluid communication with a permeate solution;

(2) administering said pharmaceutical composition to an aqueous solution to form said feed solution; and

(3) measuring the concentration of said drug in said permeate solution.

2. A method for evaluating a pharmaceutical composition comprising a drug, said method comprising:

(1) providing a microporous membrane having a plurality of pores, said membrane having a feed side and a permeate side, wherein said feed side of said membrane is in fluid communication with a feed solution, and wherein said permeate side of said membrane is in fluid communication with a permeate solution;

(2) administering said pharmaceutical composition to an aqueous solution to form said feed solution; and

(3) measuring the concentration of said drug in said permeate solution;

wherein said permeate solution comprises an organic fluid.

3. The method of claim 1 wherein said permeate solution comprises an organic fluid.

4. The method of claim 3 wherein said organic fluid is substantially immiscible with water.

5. The method of any one of claims 1-3 wherein said pores have a nominal size of about 0.02 μm to about 0.5 μm.

6. The method of claims 1 or 3 wherein said permeate side of said microporous membrane has a contact angle for a drop of water of greater than about 90° and said feed side of said microporous membrane has a contact angle for a drop of water of less than about 70°.

7. The method of claims 1 or 3 wherein said feed side of said membrane is rendered hydrophilic by treating said membrane by a process selected from treatment using a cold plasma, attachment of hydrophilic groups, absorption of a hydrophilic material, adsorption of a hydrophilic material, application of a coating that does not occlude said pores on said feed side of said membrane, and application of a coating that does occlude said pores on said feed side of said of said membrane.

8. The method of claims 2 or 3 wherein said drug has a partition coefficient between said organic fluid and water of at least 5.

9. The method of claims 2 or 3 wherein said organic fluid is selected from the group consisting of alkanes, alkenes, alcohols, ethers, ketones, aromatics, alkyl halides, and mixtures thereof.

10. The method of claim 9 wherein said organic fluid is selected from the group consisting of hexane, heptane, octane, decane, dodecane, hexadecane, cyclopentane, cyclohexane, 1 ,6-heptadiene, 1,7-octadiene, 1,8-nonadiene, 1-9- decadiene, octanol, decanol, dodecanol, isoamyl alcohol, cyclohexanol, 2- ethylhexanol, 2,6-dimethyl-4-heptanol, isopropyl ether, n-butyl ether, methyl-isobutyl ether, di-isopropyl ether, methyl-te/if-butyl ether, ethyl-terf-butyl ether, di-te/t-butyl ether, dibutyl ethylene glycol, methyl n-butyl ketone, methyl isobutyl ketone, methyl amyl ketone, methyl isoamyl ketone, diisobutyl ketone, ethyl isobutyl ketone, pentanone, hexanone, octanone, cyclohexanone, isophorone, benzene, toluene, the various isomers of xylene, ethyl benzene, nitrobenzene, nitrotoluene, cresol, methylene chloride, chloroform, carbon tetrachloride, perchloroethylene, trichloroethylene, trichloro-trifluoroethylene, tetrachloroethane, trichloroethane, dichloroethane, dibromoethane, propylene dichloride, chlorobenzene, dichlorobenzene, chlorotoluene, and mixtures thereof.

11. The method of claims 2 or 3 wherein said organic fluid comprises a mixture of at least one alkane having from 8 to 12 carbon atoms and at least one alcohol having from 8 to 12 carbon atoms.

12. The method of any one of claims 1-3 wherein said aqueous solution is selected from the group consisting of phosphate buffered saline, simulated intestinal buffer without enzymes, a model fasted duodenal solution, and a solution to model the fed state.

13. The method of any one of claims 1-3 wherein said drug is a low- solubility drug.

14. A device for performing the method of any one of claims 1 to 4 , said device comprising

(1 ) a feed reservoir for containing a feed solution,
(2) a permeate reservoir for containing a permeate solution, and
(3) a hydrophobic microporous membrane having a hydrophilic feed side and a permeate side,

wherein said membrane separates said feed reservoir from said permeate reservoir.

15. A multi-well plate for performing the method of any one of claims 1 to 4 , said multi-well plate comprising (1) a filter plate, and (2) an acceptor plate, wherein said filter plate has a plurality of filter wells, and said acceptor plate has a plurality of acceptor wells, wherein said filter wells fit into said acceptor wells, and wherein the bottom of said filter wells comprises a hydrophobic microporous membrane having a plurality of pores, said membrane having a hydrophilic feed side and a permeate side.